

February 29, 2004

Electronic Submission Via:

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Oscar Hernandez
Director
Risk Assessment Division
U.S. Environmental Protection Agency
P.O. Box 1473
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Re: American Chemistry Council Brominated Biocides Panel DMH Task Force Response to EPA Comments of November 25, 2003 on Chemical RTK HPV Challenge Submission:
5,5-Dimethylhydantoin (DMH), CAS No. 77-71-4

Dear Dr. Hernandez:

American Chemistry Council Brominated Biocides Panel DMH Task Force submitted a test plan and robust summaries on DMH to EPA on July 10, 2003. EPA reviewed the test plan and robust summaries and provided its comments to ACC on November 25, 2003. The ACC DMH Task Force's responses to EPA's November 25, 2003 comments are provided below. Each EPA original comment requiring a response is included as bold/italic font followed by the Task Force response.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

Melting point. The submitter needs to provide the reference for the experimental melting point value of 178 °C. If this is not possible, the submitter needs to provide a measured value for melting point following OECD guidelines or from a reliable literature source. A melting point estimated with MPBWIN is not sufficient for the purposes of the HPV Challenge Program unless below 0 °C.

The following reference for the melting point value was included in the submission. This reference meets the requirements of the HPV Chemical Challenge Program requirement for physical/chemical properties.

"Hawley, G. G. 1981. The Condensed Chemical Dictionary, 10th Ed. Van Nostrand Reinhold Company, Inc. New York. Page 369."

In addition to the originally cited, acceptable source, the following summarizes other melting point references for DMH:

166 – 180 °C from 18 references (reported in Bielstein MDL on STN, 2004)

178 °C from CRC Handbook of Chemistry and Physics, 66th Edition, 1985-1986 (p. C-311).

174 – 177 °C from Fluka Chemical (most pure DMH available)

The Task Force concludes that these data are adequate to meet the requirements of the HPV Chemical Challenge Program based on the consistency of the values reported in these references and the long-established values, also consistent with the above cited data, from various company literature.

Vapor pressure. The submitter presented an estimated value of 1.36×10^{-6} mm Hg at 25 °C. Estimated vapor pressure values above 7.5×10^{-8} mm Hg (1×10^{-5} Pa) are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide measured vapor pressure data, either following OECD guidelines, or from a reliable literature source.

The Task Force is not aware of any specific requirement for use of estimated values in the HPV Chemical Challenge Program. A vapor pressure of 0.00000136 mmHg indicates the chemical is essentially non-volatile which is consistent with the known properties of DMH. Further, replacing the estimated value of 1.36 E-06 with a value 2 orders of magnitude higher or the proposed minimum value of 7.5E-08 in the EPIWIN model has no significant effect on the fugacity distribution (100% release to water) as shown:

Vapor Pressure	1.36 E-04	1.36 E-06	7.5E-08
% in Air	3.14 E-06	3.14 E-06	4.2 E-06
% in Water	99.8	99.8	99.8
% in Soil	0.0016	0.0016	0.0016
% in Sediment	0.188	0.188	0.188

In addition, persistence times and other model estimates are the same or similar regardless of the vapor pressure used.

Therefore, the Task Force considers that experimentally refining the vapor pressure value at such low volatility will not provide a more reliable value nor further the understanding of the physical/chemical properties or environmental fate of DMH, and the model value is adequate to support the HPV screening dataset.

Water solubility. The submitter presented a qualitative assessment of “soluble” and a calculated value of 4516 mg/L using WSKOW v. 1.40. Qualitative and estimated water solubility values are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide measured water solubility data either following OECD guidelines or from a reliable literature source.

DMH is highly water-soluble. The EPIWIN model indicates an Experimental Database value (Bielstein) of 100,000 mg/L. Values up to 135,000 mg/L are reported in company literature. Water concentrations up to 25 grams/liter have been tested in aquatic toxicity studies. The lowest acute EC50 for aquatic toxicity is approximately 930 mg/L in a study with mysid shrimp. More importantly, the NOEC for chronic toxicity to fish is 14 ppm (14 mg/L). This value will be used for any environmental risk assessments of DMH. Lastly, using a value of 135,000 mg/L in the EPIWIN model does not change the fugacity determinations. Therefore, refining the water solubility value will not further the understanding of the physical/chemical, environmental fate, or aquatic toxicity of DMH in the HPV screening program.

The EPIWIN calculated value of 4516 mg/L is low and can be ignored.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

Fugacity. The submitter needs to recalculate the fugacity results using measured physicochemical data. Running the model using only estimated data is not adequate for the purposes of the HPV Challenge Program. The use of estimated or calculated values introduces uncertainties that then become magnified in modeling applications. Data from published sources are acceptable, as long as the submitter identifies the sources.

The data provided in the robust summary used the user-defined melting point of 178 °C and log K_{ow} of 0.35. As noted above, changes to the other requested values (vapor pressure and water solubility) have no impact

on the fugacity output from the model. Therefore, the Task Force concludes that the data as originally provided for fugacity are adequate to meet the HPV Chemical Challenge requirements.

Ecological Effects (fish, invertebrates, and algae)

EPA disagrees with the submitter's rationale, based on the predicted and measured low toxicity values for fish and invertebrates, for not conducting an algal test. EPA suggests the submitter provide SAR and data on an analog to show that the algal endpoint value would be similar to those reported for fish and invertebrates. The SAR information needs to be reported in robust summary format.

The Task Force reiterates its conclusion that the aquatic toxicity data available for DMH have been adequate for pesticide registration purposes and, therefore, meets the needs of a screening program such as the HPV Chemical Challenge Program. However, the Task Force recognizes that a determination of toxicity to aquatic plants will be valuable for risk assessment purposes beyond the scope of the HPV Chemical Challenge Program. Therefore, as a component of testing needed to complete risk assessments, the Task Force will conduct an evaluation of aquatic plant toxicity and provide the results under the framework of the HPV Chemical Challenge Program, when available.

Please feel free to call me at 703/741-5637, if you have any questions or need additional information.

Sincerely yours,

Has Shah

Has Shah
Manager, DMH Task Force

cc: Brominated Biocides Panel DMH Task Force
Jim Keith